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YOUNG, MICAH PAUL	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JIRO KANIE

Appeal 2010-009442
Application 10/826,165
Technology Center 1600

Before DONALD E. ADAMS, MELANIE L. MCCOLLUM, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134(a) involving claims to an enteral nutrition product, a method for preparing the product, and a device for administering the product. The Patent Examiner rejected the claims as

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 8-13, which are all the pending claims, are on appeal. Claim 1 is representative and reads as follows:

1. An enteral nutrition product for enteral administration, not orally, but directly to a stomach or intestines of a dysphagic patient from an external container connected to an external portion of a feeding tube provided through a through-hole of a stoma formed through a portion of the abdominal and stomach walls of the patient upon the application of pressure to said external container, said enteral nutrition product comprising:

a semi-solid material having a substantially self-supporting consistency that deforms to flow under an externally applied load without liquefying and that is capable of containing a higher concentration of a nutrient component than a liquid,

wherein said semi-solid material comprises a mixture of a liquid nutrient solution and a semi-solidifying agent comprising agar that is added to said liquid nutrient solution; and

wherein said mixture comprises said semi-solidifying agent and said liquid nutrient solution in a predetermined ratio sufficient to ensure that said self-supporting consistency of said semi-solid enteral nutrition product remains substantially unchanged before, during, and after enteral administration of said semi-solid enteral nutrition product into the patient, and said self-supporting consistency of said semisolid enteral nutrition product is further maintained within the stomach or the intestines of the patient such that said semi-solid enteral nutrition product does not liquefy due to the body temperature of the patient, to thereby prevent the patient from experiencing gastro-esophageal reflux.

The Examiner rejected the claims as follows:

• claims 8, 10, 11 and 13 under 35 U.S.C. §102(b) as anticipated by Resmer;[2] and

• claims 8-13 under 35 U.S.C. § 103(a) as unpatentable over Resmer and Kabushiki.[3]

ANTICIPATION

The Issue

The Examiner's position is that Resmer taught a semi-solid enteral formulation comprising a nutrient liquid and an emulsifying agent. (Ans. 3.) The Examiner found that Resmer disclosed that its nutrient liquid included milk products along with semi-solidifying agents such as agar-agar. (*Id.*) The Examiner also found that Resmer's product is semi-solid with a disclosed viscosity of 70 cp and is used in feeding tube devices, delivered to a patient under pressure from an exterior device. (*Id.*) Additionally, the Examiner found that Resmer disclosed forming the product by mixing the nutrient liquid with the agar-agar components along with other nutritional components at an elevated temperature, then cooled and stored. (*Id.*)

According to the Examiner, the instant claim recitation regarding application site, location of tube placement, and operating procedures of the feeding tube are directed toward a future intended use for the enteral product. (*Id.*) The Examiner found that the Resmer's enteral product is structurally, i.e., compositionally, identical to that of the instant claims, as

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[2] US Patent No. 5,232,733 issued to Paul Resmer, Aug. 3, 1993.
[3] Kabushiki et al., *Total Parenteral Nutritional and Enteral Nutrition*, 59 NIPPON RINSHO, no. 782, 283-307 (2001).

both comprise a nutrient liquid and a semi-solidifying component. (*Id.*) Additionally, the Examiner's position is that because Resmer's product comprises the compositional limitations of the claims, the product would inherently meet the instant claim limitations regarding the product maintaining its self-supporting consistency within the stomach or intestines of the patient. (*Id.* at 4.)

Appellant contends that Resmer disclosed a solution and emulsion that a skilled artisan would have "understood to exhibit liquid characteristics … and would not be sufficiently solid to exhibit the claimed semi-solid consistency characteristics or prevent the possibility of reflux." (App. Br. 11.) According to Appellant, "for an enteral nutrition product to be considered a 'semi-solid material,' in the context of claim 8, the enteral nutrition product is required to exhibit self-supporting consistency characteristics." (*Id.* at 12.) Appellant asserts that Resmer did not expressly or inherently disclose or suggest this limitation. (*Id.*) Appellant also asserts that Resmer's product is administered through a nasogastric tube rather than directly to a stomach or intestines, as instantly claimed. (*Id.* at 11.)

The issue with respect to this rejection is whether the Resmer disclosed an enteral nutrition product comprising a semi-solid material having a substantially self-supporting consistency, as claimed.

Findings of Fact

1. We agree with the Examiner's explicit findings regarding Resmer's disclosure, except for the finding that Resmer taught a semi-solid enteral formulation. (*See* Ans. 3-6.)

2. Resmer described its tube food as a "stable emulsion structure." (Resmer col. 4, l. 34.)

Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Analysis

We agree with the Examiner that the preamble recitation of administering the claimed enteral nutrition product "directly to a stomach or intestines of a dysphagic patient" refers to a future intended use for the claimed composition. As the Examiner explained, the claim body describes a structurally complete invention such that the preamble statement of purposed or intended use is not a claim limitation. (*See* Ans. 3-4, citing *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).

However, we agree with Appellant that Resmer did not disclose that its tube food comprised a semi-solid material, as claimed. While Resmer disclosed that its product comprised a liquid nutrient and agar, the reference described the resulting composition as an emulsion (FF-2) having a viscosity of 70 cp (Ans. 3). The Examiner has not provided an adequate explanation why a skilled artisan would have understood that this product would inherently have a self-supporting consistency, as recited in instant claim 8. The Examiner's explanation that the viscosity of Resmer's product "is approximately as viscous as olive oil" (Ans. 9) is insufficient, as a skilled

artisan would not consider olive oil to be a semi-solid material having a substantially self-supporting consistency.

Accordingly, we find the rejection did not establish that Resmer disclosed each and every element of the claimed invention and we reverse it.

OBVIOUSNESS

The Issue

For the obviousness rejection, the Examiner's position is that Resmer anticipated the elements of claim 8, including the limitation "a semi-solid material having a substantially self-supporting consistency...." (Ans. 5.) The Examiner combines Kabushiki solely to address elements of dependent claims 9 and 12. (*Id.* at 5-6.)

Appellant contends that because Resmer did not disclose the invention of claim 8, the rejected claims would not have been obvious over the combined prior art. (App. 14-15.) Further, Appellant asserts there are secondary considerations that rebut a prima facie case of obviousness. (*See id.* at 15-17.)

The issues with respect to this rejection are: whether the record supports the Examiner's conclusion that the cited references would have made the claimed inventions prima facie obvious, and if so, whether Appellant has provided evidence of unexpected results such that the totality of evidence weighs in favor of nonobviousness.

Principles of Law

When determining whether a claim is obvious, an Examiner must make "a searching comparison of the claimed invention – including all its

limitations – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

Analysis

We found that the Examiner did not establish that Resmer disclosed every limitation of claim 8, and we reversed the anticipation rejection over Resmer. Kabushiki does not cure Resmer's deficiency. We agree with Appellant that by relying upon Resmer as disclosing the invention of claim 8, the Examiner has not accounted for all of the limitations claims 8-13.

Accordingly, we reverse the obviousness rejection.

CONCLUSIONS OF LAW

Resmer did not disclose an enteral nutrition product comprising a semi-solid material having a substantially self-supporting consistency.

The record does not support the Examiner's conclusion that the cited references would have made the claimed inventions prima facie obvious.

SUMMARY

We reverse the rejection of claims 8, 10, 11 and 13 under 35 U.S.C. §102(b) as anticipated by Resmer; and we reverse the rejection of claims 8-13 under 35 U.S.C. § 103(a) as unpatentable over Resmer and Kabushiki.

REVERSED

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